

REMARKS

Claims 18, 21, 36 and 37 were presented for examination. Claims 18, 21, 36 and 37 were rejected. Claim 21 has been amended.

Claim Objections

Claims 21 and 36 were objected to because of the claims informalities.

Accordingly, claim 21 has been amended to correct the misspelling of the word "interatrial". However, Applicant respectfully disagrees that the word "interatrial" appears in claim 36. Therefore, Applicant requests the withdrawal of the objection to claims 21 and 36.

Rejections Under 35 U.S.C. § 102(e)

Claims 18, 21 and 36 were rejected under 35 U.S.C. § 102(e) as being anticipated by Eigler et al. Applicant respectfully traverses.

Claim 21 recites a transseptal apparatus for locating the fossa ovalis in a patient and performing a transseptal puncture of the fossa ovalis. The transseptal apparatus comprises a hollow sheath having a distal end, a transseptal needle and a catheter for use in transseptal punctures. The catheter comprises a hollow lumen, a first electrode positioned at the distal end of the catheter, and a second electrode positioned on the catheter and spaced proximally from the first electrode. The first and second electrodes are sensors of electrophysical activity of an interatrial septum. The catheter is configured to be inserted into the hollow sheath for transseptal puncture and to receive the transseptal needle urged through the lumen until a tip of the needle protrudes beyond the distal end of the catheter. The catheter removably contacts the hollow sheath. The catheter is configured such that the distal end of the catheter serves as both an electrophysiology mapping catheter for locating the fossa ovalis and a dilator suitable for penetrating the fossa ovalis during a transseptal puncture procedure by urging the catheter over the transseptal needle positioned within the lumen of the catheter. The transseptal apparatus further comprises a recording device for the generation and recording of unipolar and bipolar

electrograms. The recording device is in electrical communication with the electrodes of the catheter. The recording device generates the unipolar electrograms from the electrophysical activity of the interatrial septum sensed by the first electrode and the bipolar electrograms from the electrophysical activity of the interatrial septum sensed by both the first electrode and the second electrode.

Eigler et al disclose at least a pressure transducer permanently implantable into the left atrium which monitors the fluid pressure levels in the left atrium and relays that pressure information to the patient (Abstract, Col. 2, lines 8-22). Also, Eigler et al fails to teach two electrodes that are both positioned on a catheter for generating and recording both unipolar and bipolar electrograms from the electrophysical activity of the interatrial septum. In one embodiment, Eigler et al discloses at least one pressure transducer 62 on one lead 60 to measure the pressure in the left atrium 36 and a second pressure transducer 65 on separate lead 53 (Col. 6, lines 12-25; Col. 6, lines 55-67; Figs. 4, 5 and 8). In another embodiment, Eigler et al discloses a pressure transducer 73 on a sensor lead 77 permanently implanted in the left atrium and a second sensor 75 attached to another lead 80 (Col. 7, line 62 through Col.8, line 8; Fig. 9). However, in neither of the embodiments does Eigler et al disclose that both sensors are on the same catheter. Further, Eigler et al fails to disclose generating unipolar and bipolar electrograms from the electrophysical activity of the interatrial septum using the sensors.

Additionally, Eigler et al fails to teach that the catheter serves as both an electrophysiology mapping catheter for locating the fossa ovalis *and* a dilator suitable for penetrating the fossa ovalis. Instead, Eigler et al discloses the use of standard fluoroscopy, cardiac ultrasound, or other appropriate visualization techniques to pierce the atrial septum (Col. 3, lines 46-57). Eigler et al is also silent as to where the atrial septum is pierced. Eigler et al simply discloses that the catheter pierces the atrial septum to get to the left atrium (Col. 4, lines 15-18). Therefore, Applicant believes that claim 21 is not anticipated by Eigler et al and requests the withdrawal of the rejection to claim 21.

Independent claim 36 also recites two electrodes positioned on the catheter for generating and recording both unipolar and bipolar electrograms and that the catheter serves as both an

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electrophysiology mapping catheter for locating the fossa ovalis and a dilator suitable for penetrating the fossa ovalis as called for in claim 21. Therefore, for at least the same reasons discussed above, Applicant believes claim 36 is not anticipated by Eigler et al, and requests the withdrawal of the rejection of claim 36.

Claim 18 depends from independent claim 21 and is patentable for at least the same reasons as claim 21.

Rejections Under 35 U.S.C. § 103(a)

Claim 37 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Eigler et al. Applicant respectfully traverses this rejection.

Claim 37 depends from the independent claim 36. This dependent claim is patentable for at least the same reasons as presented above with respect to claim 36.

Conclusion

For the above reasons, the Applicant respectfully submits that the above claims are allowable. The Examiner is encouraged to contact the undersigned to resolve efficiently any formal matters or to discuss any aspects of the application or of this response. Otherwise, early notification of allowable subject matter is respectfully requested.

Respectfully submitted,
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